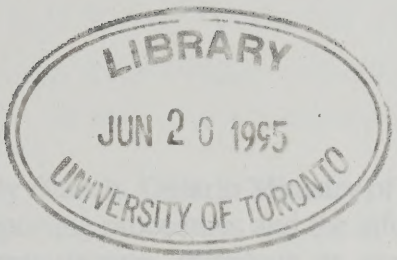
Health and Safety Guidelines

Guidelines For Notifying the Intent To Import, Manufacture, Distribute or Supply A New Agent in Ontario Workplaces Under Section 34 Of The *Occupational Health and Safety Act*

Ontario

Ministry of Labour



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I INTRODUCTION

1.1 The purpose of this Guideline

This guideline is prepared by the Occupational Health and Safety Branch, Ontario Ministry of Labour, to advise Ontario workplaces and affiliated companies on the reporting procedures and the information required for notifying the Ministry of the intent to import, manufacture, distribute or supply new agents in Ontario under section 34* of the *Occupational Health and Safety Act* (the *Act*).

1.2 Statement of section 34 of the *Act*

Subsection 34(1) of the *Act* requires any person or company who intends to import, manufacture, distribute or supply a new biological or chemical agent to first notify a Director in writing. The notice must contain the agent's composition and properties and the common or generic names of its ingredients. New biological or chemical agents which are to be used for research and development are exempted from this notification requirement.

For the purposes of this section, a new biological or chemical agent is one which has not been previously used in a workplace separate from the importer's, manufacturer's, distributor's or supplier's workplace or is one that is not listed in an inventory compiled or adopted by the Minister.

Under subsection 34(2), if the Director is of the opinion that the new agent may endanger the health or safety of a worker, the importer, manufacturer, distributor or supplier must provide a report setting out its proposed manner of use and containing information set out in clauses 54 (1) (o) (i) to (vii).

Written notices of intention to import, manufacture, distribute or supply a new agent must be addressed to:

Director
Occupational Health and Safety Branch
Ministry of Labour
400 University Avenue, 8th Floor
Toronto, Ont., M7A 1T7
Canada

Notices sent to the Director will be received in confidence.

1.3 Inventories compiled or adopted by the Minister

In January of 1981, an Order was published in *The Ontario Gazette* adopting the U.S. Environmental Protection Agency publication *The Toxic Substances Control Act Chemical Substances Inventory* for the purposes of section 21 of the *Occupational Health and Safety Act*, R.S.O. 1980, C.321.

*Please note that section 34 is renumbered from section 21 as a result of the 1990 Revised Statutes of Ontario, which came into effect December 31, 1991.

Part of the text of the Order reads as follows:

> **"ORDER MADE UNDER THE OCCUPATIONAL HEALTH AND SAFETY ACT, 1978**
>
> **INVENTORY OF AGENTS OR COMBINATION OF AGENTS FOR THE PURPOSES OF SECTION 21 OF THE ACT**
>
> **1. The Ministry of Labour hereby adopts, as an inventory of agents, or combinations of such agents* for the purposes of this section, the Chemical Substances Initial Inventory including the User Guides and Indices and Trademarks and Product Names reported in conjunction therewith of May, 1979, together with the Cumulative Supplement to the Initial Inventory of June, 1980, published by the Administrator of the Environmental Protection Agency of the United States of America under *The Toxic Substances Control Act* (P.L. 94-469)."**

The Order was originally gazetted as Ontario Regulation 1083/80. It now appears in the Revised Regulations of Ontario, 1980 as Regulation 693 with the following explanatory note added in September 1988:

> **"The June Cumulative Supplement to the Initial Inventory is no longer available from the U.S. Environmental Protection Agency. For information on this inventory, please write:**
>
> **Environmental Protection Agency**
> **Office of Toxic Substances**
> **Washington, DC 20460**
> **U.S.A.**
> **Telephone: 1-202-554-1404"**

The seven volumes of the adopted inventory (hereafter called "Inventory") are entitled:

- **Vol. I** **Initial Inventory (May, 1979)**
- **Vols. II & III** **User Guide and Indices to the Initial Inventory, Substances Name Index**
- **Vol. IV** **User Guide and Indices to the Initial Inventory, Molecular Formula and UVCB Indices**
- **Trademarks and Product Names Reported in Conjunction with the Chemical Substance Initial Inventory, Reporting Company Section**
- **Trademarks and Product Names Reported in Conjunction with the Chemical Substance Initial Inventory, Trademarks and Product Names Section**
- **Cumulative Supplement (June, 1980).**

These seven volumes are commonly referred to as the EPA or TSCA Inventory as of 1980. They are available for reference at the Ministry of Labour Library (400 University Ave., 10th Floor, Toronto, Ontario), in Occupational Health and Safety Resource Centres and in selected public, university and college libraries in Ontario. The Inventory adopted in Ontario includes substances in the EPA confidential list (i.e., Appendix B in Vol. I, Initial Inventory) but does not include substances in subsequent revisions of the EPA Inventory.

*In January 1991, amendment to the *Occupational Health and Safety Act* by Bill 208 removed the requirement to notify the intent to import, manufacture, distribute or supply a new "combination of agents."

II GENERAL INFORMATION

2.1 Definition of "agent"

A chemical agent referred to in the *Act* is any chemical substance which has a particular molecular identity, including

1) any combination of such substances occurring naturally or as a result of chemical reactions, and
2) any element or uncombined radical (e.g. OH- or NH_4^+).

A biological agent referred to in the *Act* is any biological entity (e.g., fungus, plant, animal or micro-organism) and any part or product thereof.

Two or more substances which are only mixed together physically (e.g., ethanol in water) do **not** constitute an agent.

2.2 What is a new agent?

Any agent is new unless it is listed in the adopted Inventory or has been used in an Ontario workplace other than the workplace of the importer, manufacturer, distributor or supplier.

When a new chemical agent (e.g., a polymer resin powder) is manufactured into an article (e.g., a plastic dish), the new agent within the manufactured article does not require notification. A manufactured article is any article which meets all of the following conditions:

- it is formed to a specific shape or design during manufacture;
- its intended use when in that form depends in whole or in part on its shape or design as manufactured, and
- under *normal conditions of use* it will not release or otherwise cause a person to be exposed to the new agent.

Note that "normal conditions of use" does not include the release of the new agent during the installation, maintenance or misuse of a manufactured article.

2.3 Who should notify?

Any importer, manufacturer, distributor or supplier who intends to import, manufacture, distribute or supply any new agent in Ontario is required to notify the Director of the Occupational Health and Safety Branch. There is an exception for the importation, manufacture, distribution or supply of any new agent solely for the purposes of research and development, but notification is still required from the importer, manufacturer, distributor or supplier before marketing the agent or a product containing the agent.

2.4 What should be reported in a notification?

Each notification should contain the following information:

- The identity of the agent: i.e., CAS name and number or, if a CAS number is not available, a specific chemical name and/or sufficient descriptive information (molecular formula and structural diagram, flow diagram of reaction, etc.) to identify the agent;
- The trade name of the agent;

- Its intended industrial/commercial application (e.g. paint, herbicide, etc.);
- Its physical and chemical properties (where applicable, molecular formula and weight, melting point, vapour pressure, flash point, explosive limits, solubilities, general reactivities);
- Toxicity test data or summary, or an opinion with grounds for consideration on health effects (e.g., acute oral, dermal and inhalation toxicity, skin and eye irritation, skin and respiratory tract sensitization, mutagenicity, etc.);
- Precautionary measures and personal protection, and
- WHMIS-type Material Safety Data Sheets with classification if applicable (e.g., 'controlled product,' 'D2B').

2.5 Additional information

Where the importer, manufacturer, distributor or supplier considers that additional data, information or opinions on the agent or product containing the agent (i.e., composition and toxicities) might assist with the review process, such information may be selectively submitted. Other information—such as work processes, estimated workplace quantities, operations, the size of the exposed workforce, sites of use, engineering controls, notifications in other jurisdictions, and work practices and effects on worker health in other jurisdictions—may also be selectively submitted. Such information may also be requested during the review process.

2.6 Follow-up by the notifier

The CAS number and CAS name of the new agent and any further findings of its effects on workers' health should be submitted to the Ministry as soon as they are known.

2.7 Inquiries for assistance

For further assistance, please contact the reviewers of section 34 notifications in Professional and Specialized Services, Occupational Health and Safety Branch, Ministry of Labour at (416) 326-7770.

III SCOPE OF NOTIFICATION REVIEW

3.1. The purpose and duration of the review

On behalf of the Director of the Occupational Health and Safety Branch, each notification received is reviewed by a designated staff member of the Professional and Specialized Services to ascertain:

a) the need for notification;
b) the chemical identify of the new agent;
c) the potential health and safety hazards of the new agent;
d) the adequacy of precautionary measures and personal protection recommended by the notifier for workers in the use, handling and storage of the new agent in the workplace, and
e) the classification and application of WHMIS information requirements.

The review should be completed within four weeks, at which time a response dealing with the above matters will be summarized in a letter to the notifier.

3.2 Further review and further requirement for report or assessment

Following the written responses that indicate completion of the notification review, a further review may, at any time, be conducted in light of any new findings.

Where, in the opinion of the Director, the introduction of a new agent may directly or indirectly endanger the health and safety of workers, the Director will further require the notifier to submit a report or assessment as provided for in subsection 34(2) of the *Act*. The report or assessment shall include the matters related to the new agent referred to in subclauses 54(1) (o) (i) to (vii):

> **"(i) the ingredients thereof and their common or generic name or names,**
> **(ii) the composition and the properties thereof,**
> **(iii) the toxicological effect thereof,**
> **(iv) the effect of exposure thereto whether by contact, inhalation or ingestion,**
> **(v) the protective measures used or to be used in respect thereof,**
> **(vi) the emergency measures used or to be used to deal with exposure in respect thereof, and**
> **(vii) the effect of the use, transport and disposal thereof."**

If, after reviewing the report or assessment, the Director is of the opinion that the new agent is likely to directly or indirectly endanger the health or safety of a worker, the Director may order that its use or presence be prohibited, limited, restricted or subjected to specific conditions under subsection 33(1) of the *Act*:

> **"Where a biological, chemical or physical agent or combination of such agents is used or intended to be used in the workplace and its presence in the workplace or the manner of its use is in the opinion of a Director likely to endanger the health of a worker, the Director shall by notice in writing to the employer order that the use, intended use, presence or manner of use be:**
>
> > **(a) prohibited;**
> > **(b) limited or restricted in such manner as the Director specifies, or**
> > **(c) subject to such conditions regarding administrative control, work practices, engineering control and time limits for compliance as the Director specifies."**

The order(s) may be issued to the employers at some or all affected workplaces, including the importer, manufacturer, distributor(s), supplier(s) and downstream user(s).

3.3 Field visit to work site

A field visit to the work site of use or storage *may* be made after the new agent is first imported, manufactured, distributed or supplied in Ontario. If such a visit is made the purpose will be to assess the precautionary measures taken to protect Ontario workers from any health or safety risk associated with a new agent introduced into an Ontario workplace. The field visit report which is written may contain advice on hygiene and work practices, engineering controls and medical surveillance as required.

IV CONFIDENTIALITY

4.1 The handling of submitted information and trade secrets

Trade secrets and confidential business information submitted in the notification are maintained as confidential. The notifier should also mark the submission as a confidential notification submitted under section 34 and indicate which sections of the submission are trade secrets or confidential business information. Except as required by law, no trade secret or confidential information will be released to other government agencies or members of the public. Non-confidential information (e.g., Material Safety Data Sheets) submitted may be summarized and provided to other Ministry staff for enforcement purposes. Field visit reports are not considered confidential and will not contain identifying product information.

In addition to the requirement for notification under section 34 of the *Act*, under the WHMIS legislation a new agent or product containing a new agent may be defined by the *Hazardous Products Act* as a "controlled product." The Controlled Products Regulation requires that the identity of controlled products be disclosed on product labels and Material Safety Data Sheets unless application has been made to the Hazardous Materials Information Review Commission, under the *Hazardous Materials Information Review Act*.

4.2 Freedom of Information

The Branch staff reviewing the notification on behalf of the Director are prohibited from disclosing any confidential information obtained under the *Act* even after they cease to be employed in the Ontario Civil Service. In addition, each Ontario Civil Servant is required to take an oath of office and secrecy under section 10 of the *Public Service Act*.

However, any information provided to the Ministry of Labour can be the subject of a request made under the *Freedom of Information and Protection of Privacy Act* (FOIPPA). This does not mean that the information will be disclosed, but simply that the Ministry must respond to the request by either granting or refusing access to the information. Section 17 of the FOIPPA provides an exemption for trade secrets or confidential information. Information *cannot* be released if it falls within the exemption.

The Ministry cannot provide an absolute assurance that any confidential information submitted under section 34 of the *Act* would never be disclosed. This is because any decision of the Ministry can be appealed to an external review body, the Information and Privacy Commissioner. However, the Ministry will treat the information received with the utmost confidence. The Director of the Occupational Health and Safety Branch will express any concerns regarding the release of any confidential information to the Freedom of Information Coordinator, who will consult with the notifier prior to its release.

If there are any questions about the protection that is provided by section 17 of the FOIPPA, please call the Freedom of Information and Privacy Protection Office at (416) 326-7786.

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